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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,084	07/05/2001	Nelson R. Holcomb	10010372-1	5860

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/900,084	Holcomb
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 11, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *20-35, 50, and 58-60* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *20-35, 50, and 58-60* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *0803*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 11, 2003 has been entered.

Specification

2. Claim 20 is currently amended. New claims 58-60 are added. Claims 20-35, 50 and 58-60 are pending in this application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 20-22, 25, 28, 31, 50, 58, and 60 are rejected under 35 U.S.C. 103 (a) over Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001) in view of Dusterhoft et al. (U.S. Patent 6,451,260 B1) (September 17, 2002).

Goldberg et al teach a method of high temperature hybridization in a microarray of oligonucleotides bound to a polymer surface on a siliceous substrate with a nucleic acid material (Abstract, Column 3, lines 33-39, and Column 14, lines 13-30) comprising the steps of:

incubating the nucleic acid material with the microarray of oligonucleotides on the adsorbed polymer surface in a hybridization solution at a hybridization temperature ranging from about 55 degree centigrade to about 70 degree centigrade so as to hybridize the nucleic acid material,

wherein the hybridization solution comprises a buffer composition that comprises a pH within a range of pH 6.4 to 7.5, a non-chelating buffering agent selected from 2-[N-morpholino]ethanesulfonic acid (MES) that maintains the pH within the pH range, and a

monovalent cation selected from NaCl in a concentration ranging from about 0.01 M to about 2.0 M (Column 14, lines 13-41 and Column 10, lines 6-17).

Goldberg et al. teach a method, wherein in the step of incubating, the buffer composition further comprises a chelating agent EDTA (Examples 1 and 2).

Goldberg et al. teach a method, before the step of incubating, further comprising the step of combining the nucleic acid material with the buffer composition (Example 2, Chip Pre-treatment solution).

Goldberg et al. teach a method, after the step of incubating, further comprising the step of interrogating the hybridized microarray at a first location (Example 2, Tables 1-2).

Goldberg et al do not teach a method, wherein oligonucleotides are non-covalently bound to a polymer adsorbed on the surface of a siliceous substrate.

Dusterhoft et al. teach a method, wherein oligonucleotides are non-covalently bound to a polymer adsorbed on the surface of a siliceous substrate (Column 11, line 41 to Column 12, line 20 and Column 16, line 58 to Column 17, line 31).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein oligonucleotides are non-covalently bound to a polymer adsorbed on the surface of a siliceous substrate of Dusterhoft et al. in the nucleic acid hybridization buffer of Goldberg et al. since Dusterhoft et al state, "In the final microparticle-containing filter element, the outer or inner surfaces of the enclosed microparticles are accesible to an applied liquid sample, and adsorption/immobilization of analytes contained in

the liquid sample can take place (Column 12, lines 16-20)". Moreover, Goldberg et al provide motivation as Goldberg et al state, "In another embodiment, an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, may be used in the assays, thus permitting screening and detection of binding of a large number of nucleic acids (Abstract, last sentence)". An ordinary practitioner would have been strongly motivated to combine and substitute a method, wherein oligonucleotides are non-covalently bound to a polymer adsorbed on the surface of a siliceous substrate of Dusterhoft et al. in the nucleic acid hybridization buffer of Goldberg et al. in order to improve the nucleic acid hybridization and in order to achieve the express advantages, as noted by Dusterhoft et al., of a method in which the outer or inner surfaces of the enclosed microparticles are accesible to an applied liquid sample, and adsorption/immobilization of analytes contained in the liquid sample can take place and also in order to achieve the express advantages, as noted by Goldberg et al., of an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, thus permitting screening and detection of binding of a large number of nucleic acids.

5. Claims 23, 24, and 32-35 are rejected under 35 U.S.C. 103 (a) over Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001) in view of Dusterhoft et al. (U.S. Patent 6,451,260 B1) (September 17, 2002) further in view of Reynolds et al. (U.S. Patent 6,316,608 B1) (November 13, 2001).

Goldberg et al in view of Dusterhoft et al. teach the method of claims 20-22, 25, 28, 31, 50, 58 and 60 as described above.

Goldberg et al in view of Dusterhoft et al. do not teach a method, wherein the adsorbed polymer surface comprises a polycationic polymer polyethylenediamine.

Reynolds et al. teach a method, wherein the adsorbed polymer surface comprises a polycationic polymer polyethylenediamine (Column 5, lines 22-49).

Goldberg et al in view of Dusterhoft et al. do not teach a method, further comprising the step of transmitting data representing a result of the interrogation and receiving the same at a second location remote from the first location.

Reynolds et al. teach a method, further comprising the step of transmitting data representing a result of the interrogation and receiving the same at a second location remote from the first location (Example 2, Column 11, lines 14-20).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the adsorbed polymer surface comprises a polycationic polymer polyethylenediamine further comprising the step of transmitting data representing a result of the interrogation and receiving the same at a second location remote from the first location of Reynolds et al. in the nucleic acid hybridization buffer of Goldberg et al in view of Dusterhoft et al. since Reynolds et al state, "One advantage of the present invention is that it reduces the variation in hybridization signals from element to element (Column 7, lines 37-39)". Moreover, Goldberg et al provide motivation as Goldberg et al state,

"In another embodiment, an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, may be used in the assays, thus permitting screening and detection of binding of a large number of nucleic acids (Abstract, last sentence)". An ordinary practitioner would have been strongly motivated by employing the simple scientific reasoning as well as motivations provided by Reynolds et al and Goldberg et al. to combine and substitute a method, wherein the adsorbed polymer surface comprises a polycationic polymer polyethylenediamine further comprising the step of transmitting data representing a result of the interrogation and receiving the same at a second location remote from the first location of Reynolds et al. in the nucleic acid hybridization buffer of Goldberg et al. in view of Dusterhoft et al. in order to improve the nucleic acid hybridization and in order to achieve the express advantages, as noted by Reynolds et al., of a method that can be used to reduce the variation in hybridization signals from element to element and also in order to achieve the express advantages, as noted by Goldberg et al., of an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, thus permitting screening and detection of binding of a large number of nucleic acids.

6. Claims 26-27 are rejected under 35 U.S.C. 103 (a) over Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001) in view of Dusterhoft et al. (U.S. Patent 6,451,260 B1) (September 17, 2002) further in view of Cohen (U.S. Patent 6,322,989 B1) (November 27, 2001).

Goldberg et al in view of Dusterhoft et al. teach the method of claims 20-22, 25, 28, 31, 50, 58 and 60 as described above.

Goldberg et al in view of Dusterhoft et al. do not teach a method, wherein the buffer composition further comprises an ionic surfactant SDS at a concentration ranging from about 0.01% to about 0.2% (w/v).

Cohen teaches a method, wherein the buffer composition further comprises an ionic surfactant SDS at a concentration ranging from about 0.01% to about 0.2% (w/v) (Column 19, lines 46-51 and Column 20, lines 1-5).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the buffer composition further comprises an ionic surfactant SDS at a concentration ranging from about 0.01% to about 0.2% (w/v) in the nucleic acid hybridization buffer of Goldberg et al in view of Dusterhoft et al. since Cohen states, "Those of skill will be aware that it will often be advantageous in nucleic acid hybridizations to include detergents (e.g., sodium dodecyl sulfate), chelating agents (e.g., EDTA) or other reagents in the hybridization or wash solutions (Column 19, lines 46-51)". Moreover, Goldberg et al provide motivation as Goldberg et al state, "In another embodiment, an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, may be used in the assays, thus permitting screening and detection of binding of a large number of nucleic acids (Abstract, last sentence)". An ordinary practitioner would have been strongly motivated by employing the simple scientific reasoning as well as

motivations provided by Cohen and Goldberg et al. to combine and substitute a method, wherein the buffer composition further comprises an ionic surfactant SDS at a concentration ranging from about 0.01% to about 0.2% (w/v) in the nucleic acid hybridization buffer of Goldberg et al. in view of Dusterhoft et al. in order to improve the nucleic acid hybridization and in order to achieve the express advantages, as noted by Cohen., of a method that is often advantageous in nucleic acid hybridizations to include detergents (e.g., sodium dodecyl sulfate), chelating agents (e.g., EDTA) or other reagents in the hybridization or wash solutions and also in order to achieve the express advantages, as noted by Goldberg et al., of an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, thus permitting screening and detection of binding of a large number of nucleic acids.

7. Claims 29-30 are rejected under 35 U.S.C. 103 (a) over Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001) in view of Dusterhoft et al. (U.S. Patent 6,451,260 B1) (September 17, 2002) further in view of Cohen (U.S. Patent 6,322,989 B1) (November 27, 2001) further in view of McDonough et al. (U.S. Patent 6,252,059 B1) (June 26, 2001).

Goldberg et al in view of Dusterhoft et al further in view of Cohen teach the method of claims 20-22, 25, 28, 31, 50, 58 and 60 as described above.

Goldberg et al in view of Dusterhoft et al further in view of Cohen do not teach a method, wherein the buffer composition further comprises a monovalent cation LiCl at a concentration greater than or equal to 300 mM.

McDonough et al. teach a method, wherein the buffer composition further comprises a monovalent cation LiCl at a concentration greater than or equal to 300 mM. (Column 4, lines 2-10, and Column 8, lines 15-50).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the buffer composition buffer composition further comprises a monovalent cation LiCl at a concentration greater than or equal to 300 mM of McDonough et al in the method of Goldberg et al.in view of Dusterhoft et al further in view of Cohen since McDonough et al state, "In a related aspect, the invention features the formation of nucleic acid hybrids formed by the hybridization of the probes of this invention with target nucleic acids under stringent hybridization conditions. Stringent hybridization conditions involve the use of 0.6 M LiCl at 60 degree centigrade. The hybrids are useful because they allow the specific detection of viral nucleic acid (Column 4, lines 3-10)". Moreover, Goldberg et al provide motivation as Goldberg et al state, "In another embodiment, an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, may be used in the assays, thus permitting screening and detection of binding of a large number of nucleic acids (Abstract, last sentence)". An ordinary practitioner would have been strongly motivated by employing the simple scientific reasoning as well as motivations provided by McDonough et al and Goldberg et al. to combine and substitute a method, wherein the buffer composition buffer composition further comprises a monovalent cation LiCl at a concentration greater than or equal to 300 mM of McDonough et al in the

method of Goldberg et al. in view of Dusterhoft et al further in view of Cohen in order to improve the nucleic acid hybridization and in order to achieve the express advantages, as noted by McDonough et al., of a method that provides nucleic acid hybrids made under stringent conditions that are useful because they allow the specific detection of viral nucleic acid and also in order to achieve the express advantages, as noted by Goldberg et al., of an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, thus permitting screening and detection of binding of a large number of nucleic acids.

8. Claim 59 is rejected under 35 U.S.C. 103 (a) over Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001) in view of Dusterhoft et al. (U.S. Patent 6,451,260 B1) (September 17, 2002) further in view of Milliman et al. (U.S. Patent 6,495,327 B2) (December 7, 2002).

Goldberg et al in view of Dusterhoft et al. teach the method of claims 20-22, 25, 28, 31, 50, 58 and 60 as described above.

Goldberg et al in view of Dusterhoft et al. do not teach a method, wherein the buffer composition further comprises the monovalent cation LiCl at a concentration of greater than or equal to 300 mM.

Milliman et al. teaches a method, wherein the buffer composition further comprises the monovalent cation LiCl at a concentration of greater than or equal to 300 mM (600 mM used by Milliman to be precise) (Column 4, lines 9-17).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time

the invention was made to combine and substitute a method, wherein the buffer composition further comprises the monovalent cation LiCl at a concentration of greater than or equal to 300 mM of Milliman et al. in the nucleic acid hybridization buffer of Goldberg et al in view of Dusterhoft et al. since Milliman et al. states, "Examples of useful high stringency hybridization conditions that can be used in the second step of the method include 0.6 M LiCl (Column 6, lines 9-12)". An ordinary practitioner would have been strongly motivated to combine and substitute a method, wherein the buffer composition further comprises the monovalent cation LiCl at a concentration of greater than or equal to 300 mM of Milliman et al. in the nucleic acid hybridization buffer of Goldberg et al in view of Dusterhoft et al. in order to improve the nucleic acid hybridization and in order to achieve the express advantages, as noted byMilliman et al., of an useful high stringency hybridization conditions that include 0.6 M LiCl.

Response to Amendment

9. In response to amendment, previous 102(a) and 103(a) rejections are hereby withdrawn. However, new 103(a) rejections have been included.

Response to Arguments

10. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau, whose telephone number is (703) 605-1237.

Arun Kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner

September 8, 2003

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